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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,379	01/16/2001	Holger Rauth	100564-09055	1266
6449	7590	10/01/2003	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			KAM, CHIH MIN	
		ART UNIT	PAPER NUMBER	
		1653	20	
DATE MAILED: 10/01/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/760,379	RAUTH ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Chih-Min Kam	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 September 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,5-9,11,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,5-9,11,14 and 15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

1. The finality of the previous Office Action (Paper No.14) is withdrawn because of a new ground of rejection.

### ***Status of the Claims***

2. Claims 1, 5-9, 11, 14 and 15 are pending.

Applicants' amendment filed on September 5, 2003 (Paper No. 16) is acknowledged, and applicants' response has been fully considered. Claims 1, 5 and 15 have been amended, and claims 10 and 13 have been canceled. Thus, claims 1, 5-9, 11, 14 and 15 are examined.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claims 1, 5-11 and 13-15 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at pages 4-5 in Paper No. 16.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5, 6, 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Guo *et al.* (Disi Junyi Daxue Xuebao 20 (1), 85-88, 1999). An English translation of the reference will be forward to applicants when it is obtained.

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Guo *et al* teach a method for purifying recombinant human interferon- $\alpha$  (rhIFN- $\alpha$ ) using magnetic affinity microsphere (MAMS, abstract). The magnetic agarose microsphere is prepared from magnetic powders ( $\text{Fe}_3\text{O}_4$ ; claim 5) embedded in agarose and rhIFN- $\alpha$  monoclonal antibody was linked to matrix by CNBr method (page 86, paragraph 1), where the OH group on the surface can be modified to different functional groups (page 86, paragraph 2; claim 8) and the pore size of the matrix is about 1  $\mu\text{m}$  (Fig. 1). The solution containing rhIFN- $\alpha$  is mixed with MAMS and leaves overnight; the MAMS is removed from the solution and subsequently washed with PBS buffer (claim 11); and rhIFN- $\alpha$  is then eluted from MAMS and separated from the MAMS by magnetic separation, the purity is checked by SDS-PAGE (page 87, paragraph 2.4; claim 1). Monoclonal antibody, which is linked to the matrix, would contain many hydrophilic amino acids such as Ser and Thr, and hydrophobic amino acids such as Val, Leu and Phe which have aryl or alkyl side chain on the surface (claim 6).

5. Claims 1, 5, 6, 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Margel *et al.* (Analytical Biochemistry 128, 342-350 (1983)).

Margel *et al* teach a method for purifying antibodies using magnetic agarose-polyaldehyde microsphere beads conjugated with proteins, where magnetic agarose-polyaldehyde microsphere beads having the diameters of 50-150  $\mu\text{m}$  were produced by carrying out the encapsulation of the microspheres in the presence of ferrofluidic material (page 342, right column; claim 5) and the magnetic agarose-polyaldehyde microsphere beads with or without bound spacer are coupled with appropriate antigen such as BSA in PBS to form immunoadsorbent (page 344, right column; page 345). The immune serum was passed through a column containing immunoadsorbent, the immunobeads were then washed with PBS (claim 11),

antibodies were eluted with 0.2 M glycine-HCl buffer at pH 2.4, where the removal of unbound antibodies and the washing steps were achieved by successive decantation with a magnetic field (page 345-page 346, left column; Table 5; claim 1). The antigen such as BSA, which is linked to the micosphere, would contain many hydrophilic amino acids such as Ser and Thr having hydroxyl side chain, and hydrophobic amino acids such as Val, Leu and Phe which have aryl or alkyl side chain on the surface (claim 6), and the agarose beads also contains many hydroxyl group on the surface (claim 8).

6. Claims 7, 9, 14 and 15 are rejected because they are dependent from a rejected claim.

*Conclusion*

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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September 28, 2003

*Christopher S. F. Low*  
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